SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):
COLOPLAST A/S; COLOPLAST CORP.; COLOPLAST MANUFACTURING US, LLC; and DOES 1 to 20

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):
CRISTY DAVIS

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

FILED
MAY 31 2022
R. BICKER CLERK OF THE COURT
SUPERIOR COURT OF CALIFORNIA
COUNTY OF CONTRA COSTA
By M. Macapinlac Deputy Clerk

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. *¡AVISO! Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

Tiene 30 DIAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 o más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es):
Contra Costa County Superior Court
725 Court Street, Martinez, CA 94553

CASE NUMBER: *(Número del Caso):*
C22-01086

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is: *(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):*
Christopher B. Dolan, Esq (165358), Dolan Law Firm, PC 1438 Market Street, San Francisco, CA 94102 T: (415)421-2800

DATE: *(Fecha)* MAY 31 2022 Clerk, by *(Secretario)* M. Macapinlac Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☑ on behalf of (specify): Coloplast Corp.
   under: ☑ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☐ by personal delivery on *(date):*

Page 1 of 1

Form Adopted for Mandatory Use
Judicial Council of California
SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
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Christopher B. Dolan, Esq. (SBN 165358)
Allison L. Stone, Esq. (SBN 274607)
Cioffi C. Remmer, Esq. (SBN 262663)
Taylor French, Esq. (SBN 317880)
DOLAN LAW FIRM, PC
1438 Market Street
San Francisco, California 94102
Telephone: (415) 421-2800
Facsimile: (415) 421-2830

Attorneys for Plaintiffs,
CRISTY DAVIS

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF

CRISTY DAVIS,

Plaintiff,

v.

COLOPLAST A/S, COLOPLAST CORP., COLOPLAST MANUFACTURING US, LLC, AND DOES 1 to 20, inclusive,

Defendants.

CASE NO.: C22-01086

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. Strict Products Liability - Consumer Expectations Test
2. Strict Products Liability - Risk-Benefit Test
3. Strict Products Liability - Failure to Warn
4. Strict Products Liability Manufacturing Defect
5. Negligence
6. Breach of Express and Implied Warranty
7. Fraud
8. Negligent Misrepresentation
9. Fraud by Concealment

DEMAND FOR JURY TRIAL

All allegations in this Complaint are based upon information and belief except for those allegations which pertain to the Plaintiff named herein and her counsel. Each allegation in this Complaint either has evidentiary support or is likely to have evidentiary support after reasonable opportunity for further investigation and

discovery. Plaintiff, for her causes of action against these Defendants, alleges as follows:

NATURE OF CASE

1. Plaintiff Cristy Davis, by her undersigned counsel, brings this Complaint against Coloplast Corp. and Coloplast Manufacturing US, LLC, and DOES 1 through 50, (collectively referred to herein as "Defendants") related to the design, manufacture, marketing, distribution and sale of Defendants' Supris® Retropubic Sling System that was implanted in Plaintiff Cristy Davis. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon her individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Defendants' actions and misconduct and alleges as follows:

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to California Code of Civil Procedure § 410.10.

3. Jurisdiction is proper in this case in that the amount in controversy is in excess of the statutory requirements of this Court.

4. Venue is proper in this Court pursuant to California Code of Civil Procedure §§ 395 and 395.5 because the incident and injuries to Plaintiff herein occurred in the City of Martinez, County of Contra Costa County.

PLAINTIFFS

5. Plaintiff Cristy Davis is, and was, at all relevant times mentioned herein:

a. A resident of the City of Martinez, State of California; and

b. Injured by Defendants' conduct in the city of Martinez, State of California.

DEFENDANTS

6. Plaintiff is informed and believe, and based upon that information and belief allege, that Defendant Coloplast Corp., is and was, at all relevant times mentioned herein:

a. At all times relevant a wholly owned U.S. sales and marketing subsidiary of Coloplast A/S which is the exclusive owner of multiple U.S. Patents for Surgical Device Implantable to Treat Female Urinary Incontinence, Method and Device for Treating Urinary Incontinence, and Implantable Device Configured to Treat Pelvic Organ Prolapse.

b. A corporation incorporated in the state and according to the laws of the state of Delaware.

c. At all times relevant herein operated its principal place of business at 1601 West River Road North, Minneapolis, Minnesota.

d. At all times relevant, Coloplast Corp. was in the business of developing, designing, licensing, advertising, delivering, manufacturing, packaging, labeling, marketing, selling, and distributing the Supris® Retropubic Sling System a transvaginal mesh

product, which was implanted in Plaintiff Cristy Davis and caused her injuries.

7. Plaintiff is informed and believes, and based upon that information and belief alleges, that Defendant Coloplast Manufacturing US, LLC, is and was, at all relevant times mentioned herein:

a. At all times relevant a wholly owned subsidiary of Coloplast Corp. as its principal member.

b. A limited liability corporation incorporated in the state and according to the laws of the state of Minnesota.

c. At all times relevant herein operated its principal place of business at 1601 West River Road North, Minneapolis, Minnesota and/or 1010 Dale Street North, St. Paul, Minnesota 55117.

d. At all times relevant, Defendant Coloplast Manufacturing US, LLC, was in the business of developing, designing, licensing, advertising, delivering, manufacturing, packaging, labeling, marketing, selling, and distributing the Supris® Retropubic Sling System a transvaginal mesh product, which was implanted in Plaintiff Cristy Davis and caused her injuries.

8. Plaintiff is informed and believes and based upon that information and belief alleges that DOES 1-10, and each of them are or at all relevant times were persons who directly market, instructed, and advised the physicians in the method and manner of

the surgical application of the product and as such were an integral part of the marketing, sale, distribution, and use of the product.

9. Plaintiff is informed and believes and based upon that information and belief alleges that DOES 11-15, and each of them are or at all relevant times were persons who distributed the product.

10. Plaintiff is informed and believes and based upon that information and belief alleges that DOES 16-20, and each of them are or at all relevant times were sales representatives who marketed, promoted, and sold the product.

11. Plaintiff is informed and believes, and based upon that information and belief alleges, that each Defendant named in this Complaint is responsible in some manner for one or more of the events and happenings, and proximately caused the injuries and damages, hereinafter alleged.

12. Plaintiff is informed and believes, and based upon that information and belief alleges, that each Defendant named in this Complaint is, and at all times mentioned herein was, the agent, servant, and/or employee of each of the other Defendants, and that each Defendant was acting within the course and scope of his, her, or its authority as the agent, servant, and/or employee of each of the other Defendants. Consequently, each Defendant is jointly and severally liable to Plaintiff for the damages sustained as a proximate result of their conduct.

13. Plaintiff is informed and believes, and based upon that information and belief alleges, that each Defendant named in this Complaint, are, and at all times mentioned herein were working jointly and in concert with one another to further their business of developing, designing, licensing, distributing, selling, marketing,

advertising, and delivering, and introducing into interstate commerce within the United States transvaginal mesh products, specifically the Supris® Retropubic Sling System. At all times relevant hereto, each of the Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other and was acting within the scope of this respective authority by virtue of those interrelationships.

14. Plaintiff is informed and believes, and based upon that information and belief alleges, that each Defendant named in this Complaint, are, and at all times mentioned herein were individuals, sometimes referred to as detail persons, who provided instruction and guidance to Plaintiff Cristy Davis's physicians on how to market, sell and in the method and/or manner to perform surgery utilizing Defendants' mesh products in conjunction with care and treatment provided to her.

FACTUAL BACKGROUND

15. At all relevant times, Defendants were in the business of developing, designing, licensing, advertising, delivering, manufacturing, packaging, labeling, marketing, selling, and distributing the Supris® Retropubic Sling System (the "Product" or "Supris®"), a transvaginal mesh product, which was implanted in Plaintiff Cristy Davis ("Plaintiff" or "Mrs. Davis").

16. Defendants' pelvic mesh products, including the Supris®, used to treat stress urinary incontinence, and/or pelvic organ prolapse contain monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this

material as implanted in Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population, including the Plaintiff, who are implanted with pelvic mesh products, including the Product.

17. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh, including:

a. The formation of scar tissue;

b. Ongoing scarification;

c. Mesh contraction;

d. Ongoing chronic inflammation related to chronic foreign body reactions; mesh degradation exacerbated by chronic infections and bio-films;

e. Deformation of the mesh;

f. Loss of pore size with tension;

g. Fibrotic bridging leading to scar plate formation and mesh encapsulation; and

h. Shrinkage/contraction of the encapsulate mesh.

18. When pelvic mesh products, including the Product, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition with mechanical mismatch in the pelvis leading to a multitude of injuries including, but not limited to, the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic, vaginal, groin and leg pain, recurrence, worsening incontinence, chronic dyspareunia, injury or irritation of the obturator, pudendal and other pelvic nerves, injury or irritation of the muscles and soft tissues of the pelvis, wound infection, rejection of the mesh, tissue

necrosis and irritation, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to urethra, pelvic abscess formation, hematoma, risk of infection, and/or the need for additional surgeries, among others. As a result, Defendants' mesh is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

19. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. Then, in the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence("SUI").

20. In 1996, the U.S. Food and Drug Administration (FDA) cleared the first pelvis mesh products for use in the treatment of stress urinary incontinence (SUI). These products included products manufactured, marketed, and distributed by Defendants. These products are approved by the FDA under the abbreviated 510(k) approval process.

21. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the pelvic mesh products, including the Product at issue in this case.

22. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with

surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

23. The FDA Safety Communication also stated,

> "*Mesh contraction* (shrinkage) *is a previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA… Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in the original).

24. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

25. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

26. The injuries of Plaintiff, as will be more fully established in Discovery, are identical to those reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

27. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

28. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

29. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

30. The FDA White Paper further stated that, "these products are associated with serious adverse events… compounding the concerns regarding adverse events are performance data that fail to

demonstrate improved clinical benefit over traditional non-mesh repair."

31. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

32. As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

33. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

34. Coloplast actively marketed that the Supris® sling was "biocompatible."

35. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life

altering and might not always be surgically correctable."[1] Furthermore, the data revealed that the women who received both MUS and TVM[2] represented a complicated surgical group. Of the 58 women, 36% had undergone initial mesh removal attempts before their referral to either tertiary institution, 29% required re-excision of residual mesh, 13 once and 4 twice, five women (7%) developed recurrent symptomatic pelvic organ prolapse, and the residual rate of dyspareunia and pelvic pain was 14% and 22%, respectively.

36. Defendants did not, and have not, adequately studied the extent of the risks associated with their pelvic mesh products, including the Supris® sling. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

37. An Investigational Device Exemption ("IDE") clinical study of the Supris® sponsored by Coloplast was submitted to the FDA to support market clearance[3] (the "Study").

38. The Study was first published in 2014 for one-year data and in 2017 for two-year data and revealed that mesh extrusion was reported in 3.5% of subjects, one of which required two revision surgeries. The Study reports "[n]on-pelvic pain--other" pain occurring in eight percent of subjects studied. Because the device implants into the obturator internus at the obturator foramen the

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[1] Lee D, Dillon B, Lemack G, Gomelsky A, Zimmern P. *Transvaginal mesh kits--how "serious" are the complications and are they reversible?*. Urology. 2013;81(1):43-48. doi:10.1016/j.urology.2012.07.098.

[2] MUS: Mid-urethral sling; TVM: Transvaginal Mesh.

[3] Kocjanic E, Erickson T, Tu L-M, Gheiler E, Van Drie D. *Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence*. Neurology and Urodynamics 36:1582-1587(2017). https://doi.org/10.1002/nau.23156

"[n]on-pelvic pain--other" suggests that the pain is located in the groin region.

39. On May 25, 2012, Defendants submitted a new traditional 510(k) premarket notification for the Supris®. The predicates to which substantial equivalence was claimed included the Aris Sling System, the AMS MiniArc Sling System, and the Bard Ajust Adjustable Single Incision Sling. All three of these devices use the same mesh originally designed for the Aris product.

40. On November 5, 2012, Defendants sought and obtained FDA clearance to market the Supris® sling, intended for treatment of Stress Urinary Incontinence, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. According to the Coloplast U.S. website, the Supris® sling material is the same as the Coloplast legacy products of Aris."[4] No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Coloplast with regard to the Supris® sling.

a. In May 2005, Mentor announced the U.S. launch of its new Aris™ Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.™), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of

[4] Coloplast, Altis®, Product information & Resources, Product description, http://www.coloplast.us/supris-en-us.aspx#section=product-description_3 (last visited May 31, 2020).

stress urinary incontinence in women." Analytic Biosurgical Solutions ("ABISS") FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

b. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398 including inter alia, Mentor's October 12, 2005 agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

c. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

d. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

e. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The

Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

f. Coloplast Corp.'s annual report for 2009-2010 reported that "the majority of our acquired patents and trademarks are associated with the acquisition of Mentor's urology business in 2006." The annual report also said that Mentor signed a "non-competition clause prohibiting Mentor (the seller) from selling urology products for the next seven years…"

g. Coloplast Corp. began marketing the Exair Prolapse Repair System in May 2009 to treat pelvic organ prolapse. This product is made of NovaSilk Mesh, precut into the necessary shape with four mesh arms extending from the main body, which are used to implant the device. This product obtained 510(k) clearance based on its substantial equivalence with Coloplast Corp.'s (formerly

Mentor's) NovaSilk Mesh, and Gynecare Prolift Total Pelvic Floor Repair System cleared under pre-market notification number K071512 on May 15, 2008.

h. Coloplast A/S received 510(k) clearance for the Supris Retropubic Sling System 510(k) 111233 in June 2011, as a device substantially equivalent to the Mentor Aris Suprapubic Surgical Kit.

i. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Mpathy was founded in 2003, with the aim of developing less invasive surgical solutions for the treatment of female stress urinary incontinence and pelvic organ prolapse. Mpathy's core product lines included Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. Defendant Coloplast Corp. said of the acquisition that Coloplast Corp.'s market position in Surgical Urology and Female Pelvic Health would immediately strengthen based on Mpathy's product portfolio including slings, mini-slings and meshes for stress urinary incontinence and pelvic floor repair and material portfolio including Smartmesh® technology.

j. Coloplast Corp.'s website describes its various products, including those for treating (i) "Pelvic Organ Prolapse" and (ii) "Stress Urinary Incontinence," including "Sling Procedures." A press release issued by Coloplast Corp. described Coloplast Corp.'s new corporate headquarters at 1601 West River Road in Minneapolis and stated that "Denmark-based Coloplast…selected north Minneapolis as

the new home for its North American headquarters in June 2006." According to the press release the new headquarters "will include one of the company's three global Innovation Centers."

41. In Defendants' June 24, 2011 510(k) Summary (K111233) for the product at issue, Defendants state Supris® is substantially similar in performance, indications, design and materials to Coloplast's Aris System (previously Mentor's) …" The American Medical System's MiniArc System and C.R. Bard Adjust Adjustable Single System Sling were also listed as substantially equivalent predicate devices. In the Device Description section, the Summary further states: "The sling material is manufactured using the commercialized Aris polypropylene mesh (K050148)".

42. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[5]

43. Defendants knew or should have known about their Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

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[5] U.S. Food & Drug Administration, *Urogynecological Surgical Mesh Implants*, http://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited May 31, 2020).

44. Defendants knew or should have known that their pelvic mesh products, including the Supris® sling, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives designs and feasible alternative procedures that do not involve the same risks.

45. At the time Defendants began marketing each of the Supris® sling, Defendants were aware that the Product was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

46. The scientific evidence shows that the material from which the Supris® sling is made is biologically incompatible with human tissue and not inert as it promotes a negative immune response in a large subset of the population implanted with the Supris® sling, including Plaintiff Cristy Davis.

47. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

48. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Supris® sling was unreasonably susceptible to degradation and fragmentation inside the body.

49. Defendants make the following statements regarding their products:

> [Supris has] Low rate of particle release from the sling-**minimizes increase in inflammatory response**. Atraumatic, smooth edges allow for easy passage during implantation. Macroporous design allows for optimal tissue integration. (emphasis added).

50. Contrary to Defendants' assertions that its products minimize increase in inflammatory response:

a. In September of 2009, results from a study were published in the BMC Women's Health relating to the comparison of host response and complications in patients implanted with Coloplast's Aris. Implants from the Aris group showed **an increase risk of erosion which was quantified at 4%, reintervention at 3%, de novo dyspareunia at 5%, de novo urgency at 2%, perineal pain at 2%, and worsening of urgency at 3%.**[6]

b. In September of 2012, results from a study were published in the World Journal of Urology relating to the comparison of TVT vs TOT slings. 15 of 71 patients suffered adverse events including infection and erosion, **two thirds of which were implanted with the Aris.**

51. Defendants make the following statements regarding their products:

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[6] Kaelin-Gambirasio I, *Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up*. BMC Womens Health. 2009 Sep 25; 9:28.

> Novasilk is one of the lightest weight, thinnest mesh's on the market, which translates into a more conforming mesh that may reduce cases of inflammation, infection, or erosion by having less implanted material.

52. Contrary to Defendants' assertions that its products are resistant to significant inflammation, infection, or erosion:

a. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. [painful sexual intercourse].[7]

b. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina.[8]

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[7] Cosson, M., et al., *Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?* Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.* Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

[8] Dora, C.D., et al., *Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery.* J Urol, 2004. 171(5): p. 1970-3.

c. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection.[9]

d. In a study published in August of 2012, Defendants' Novasilk was compared to other polypropylene on the market relating structural properties. Novasilk was found to have less porosity and increased stiffness than several of the other studied products supporting clinical observations among plaintiffs' surgeons and the causative conclusion that properties of Defendants' mesh led to plaintiffs' complications.[10]

53. Defendants' pelvic mesh products, including the product at issue and its predecessor products, were and are unreasonably susceptible to degradation and fragmentation inside the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response within and adjacent to the soft tissue and vital structures within the pelvis; chronic wound healing; chronic infections in and around the mesh fibers; nerve entrapment in the collagen scar formation; and traction injuries to nerves from collagen scar formation. Defendants knew or should have known of these serious risks and should have, therefore, warned

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[9] Birch C, Fynes MM. *The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery.* Curr Opin Obstet Gynecol. 2002; 14:527-595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. *High complication rate identified in sacrocolpopexy patients attributed to silicone mesh.* J Urol. 2005; 65:1099-1103.

[10] Feola A, *Characterizing the ex vivo textile and structural properties of synthetic prolapse mesh products.* Int Urogynecol J. 2012 Aug 11.

physicians and patients regarding these risks; to the extent they were known or knowable.

54. The Supris® sling was unreasonably susceptible to shrinkage and contraction inside the body. Defendants knew or should have known of this serious risk and warned physicians and patients.

55. The Supris® sling has been and continues to be marketed by Defendants to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe, effective, and minimally invasive surgical techniques, and as safe and more effective as compared to available feasible alternative treatments of stress urinary incontinence, and other competing products.

56. A woman who elects to have her SUI or POP surgically treated has several options:

a. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure") which eliminates polypropylene mesh related complications and is not associated with chronic, life altering, intractable pain.

b. SUI can also be corrected by using an autologous sling with tissue harvested from the fascia of the abdominal wall or the tissue from the leg that eliminates polypropylene mesh related complications and is not associated with chronic, life-altering, intractable pain.

c. SUI can also be surgically addressed using synthetic materials injected under the urethra to provide support.

d. POP can be corrected through abdominal or transvaginal surgery and using traditional suture repair, thereby

avoiding mesh related complications with no significant change in efficacy.

e. POP can also be corrected by transvaginal repair with biologic materials thereby reducing polypropylene mesh related complications with no significant change in efficacy.

f. POP can also be repaired with abdominally synthetic materials, including polypropylene mesh devices, avoiding contamination of the polypropylene mesh material with bacteria from the vagina and reducing the risk of neurological injury from blind placement or at best with limited visualization of the vaginal mesh polypropylene devices.

57. Defendants deliberately misrepresented and/or negligently misrepresented, and/or concealed, and/or omitted, and/or downplayed the risks, dangers, defects, and disadvantages of their Products, including the Supris® sling, and advertised, promoted, marketed, sold and distributed the Supris® sling as a safe medical device when Defendants knew or should have known that the Supris® sling was not safe for its intended purposes, and that the Supris® sling would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries.

58. Defendants provided instructional seminars using the services of physicians, including DOES 1-10, wherein the physicians acted as actual or ostensible agents of Coloplast, extorted the virtues and efficacy of the sling while deliberately misrepresenting, negligently misrepresenting, concealing, omitting, and/or downplaying

the risks, dangers, defects, and disadvantages of the product, including the Supris® sling.

59. Further, while some of the problems associated with the Supris® sling were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

60. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Supris® sling has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

61. The specific nature of the Supris® sling's defects includes, but is not limited to, the following:

a. The use of polypropylene in the Supris® sling and the immune reactions that result from such material, causing adverse reactions and injuries, including but not limited to, painful recurrent erosions and associated intractable pain;

b. The Supris® sling was not "biocompatible."

c. The design of the Supris® sling to be inserted blindly into and through an area of the body that is blood vessel rich, nerve dense, with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries, including but not limited to, excessive blood loss and vascular damage, permanent nerve injury and

associated chronic, intractable neuropathic pain. The contaminated permanently-implanted mesh will cause chronic infections and biofilms, and will enhance the chronic inflammatory response–leading to chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injury to the soft tissues, nerves, and vital structures of the pelvis;

d. Biomechanical issues with the design of the Supris® sling, including but not limited to, the propensity of the Supris® sling to contract or shrink inside the body, that in turn causes surrounding tissue to be eroded, inflamed, fibrotic, and contract, resulting in serious and permanent injury to the soft tissue, nerves, and vital structures of the pelvis;

e. The use and design of arms and hooked anchors, referred to as the tissue fixation devices, in the Supris® sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure muscles, vascular structures, and major nerve routes in the pelvic region;

f. The propensity of the Supris® sling to deform when subject to prolonged tension both during implantation and once implanted inside the body, causing the mesh, or portions thereof, to become encapsulated and contract in a rigid scar plate thereby leading to nerve entrapment, nerve traction, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response of soft

tissue leading to chronic pain from muscle damage or irritation and chronic pain from nerve damage or irritation;

g. The inelasticity of the Supris® sling which is potentiated by the negative immune response, degradation, and encapsulation by scar tissue creates a mechanical mismatch between the mesh and the delicate, sensitive areas of the vagina and pelvis where the product is implanted, thereby causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, walking);

h. The propensity of the Supris® sling for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, a "barbed wire" or "saw blade" effect as a result of the fragmented surface "sawing" through the tissue and leading to bacteria harboring in the fragmented, peeled and split fiber surface, which in turn leads to chronic infections a the mesh surface, and results in continuing injury over time to the soft tissue, nerves, and vital structures of the pelvis;

i. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions; and

j. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into

the pelvic tissue and preventing the safe removal and/or excision of the mesh once a complication occurs.

62. The Supris® sling is also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Supris® sling's propensities to contract, retract, and/or shrink inside the body;

b. The Supris® sling's propensities for degradation, fragmentation, and/or migration;

c. The Supris® sling's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Supris® sling;

f. The risk of chronic infections resulting from the Supris® sling;

g. The risk of permanent vaginal or pelvic scarring as a result of the Supris® sling;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual intercourse resulting from the Supris® sling;

j. The risk of recurrent, intractable pelvic pain from muscle injury, irritation, nerve injury, or other pain resulting from the Supris® sling;

k. The need for corrective or revision surgery to adjust or remove the Supris® sling, which in some cases is neither feasible nor possible;

l. The risk of ongoing, intractable pain from muscle injury or irritation or nerve injury or irritation and other pain that persist after attempted surgical removal of the Supris® sling;

m. The severity of complications that could result from implantation of the Supris® sling, both acutely after implantation and those that occur overtime;

n. The hazards associated with the Supris® sling;

o. The Supris® sling's defects described herein;

p. Treatment of stress urinary incontinence with the Supris® sling is no more effective than feasible available alternative procedures and feasible available designs;

q. Treatment of stress urinary incontinence with the Supris® sling makes future surgical repair more difficult than feasible available alternative procedures and feasible available designs;

r. Use of the Supris® sling puts the patient at a greater risk of requiring additional surgery than feasible available alternative procedures and feasible available designs;

s. Removal of the Supris® sling due to complications may involve multiple surgeries and may significantly impair the patient's quality of life and may not be successful in the treatment of chronic intractable pain from muscle damage or irritation or from nerve damage or irritation;

t. Complete removal of the Supris® sling may not be possible and may not result in complete resolution of the complications, including pain; and

u. The nature, magnitude, and frequency of the complications that patients, such as Plaintiff Cristy Davis, risk as a result of the Supris® sling device implantation.

63. Defendants underreported and continue to underreport information about the propensity of their products, including the Supris® sling, to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Supris® sling through various means and media.

64. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude, and frequency of the risks attendant to the Supris® sling.

65. Defendants failed to design and establish a safe, effective procedure for removal of the Supris® sling, or to determine if a safe, effective procedure for removal of the Supris® sling exists.

66. Feasible and safer alternative designs and feasible and safer alternative procedures to the Supris® sling have existed at all times relevant that do not present the same frequency or severity of risks as do the Supris® sling.

67. The Supris® sling was at all times utilized and implanted in a manner intended and foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained implanting physicians.

68. Defendants, including DOES 1-10, knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Supris® sling and the aftercare of patients implanted with the Supris® sling.

69. The Supris® sling implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendants'

possession, and in the condition directed by and expected by Defendants.

70. The injuries, conditions, and complications suffered by Plaintiff, and numerous women around the world who have been implanted with the Supris® sling include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), urinary dysfunction, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage or irritation, obturator nerve damage or irritation, pelvic floor damage or irritation to soft tissues including muscles, and chronic pelvic pain from muscle damage and irritation, and chronic pain from nerve damage and irritation, emotional distress and mental anguish, and other debilitating complications that impair mobility, sitting tolerance, bowel and bladder function, and sexual function.

71. In addition, affected women, including Plaintiff, will require continuous monitoring and treatment as a result of the Defendants' Supris® sling implant.

72. Monitoring procedures exist for individuals experiencing physical and mental injuries, such as Plaintiff, from mesh implanted in patients with stress urinary incontinence. The monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles. As such, Plaintiff is entitled to future medical monitoring and treatment directly related to the existing injuries caused by the defective products.

73. In many cases, including Plaintiff's, women have been forced to undergo extensive medical treatment including, but not

limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

74. The medical and scientific literature studying the effects of mesh products like the Supris® sling, the product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to mesh products.

75. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

76. At all relevant times herein, Defendants continued to promote the Supris® sling as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety. Plaintiff reasonably relied upon the statements of Defendants and as a reasonable consumer, Plaintiff had the right to expect that the Product would perform as promised.

77. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Supris® sling, including the magnitude and frequency of these risks.

78. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff Cristy Davis, her treating physicians, the medical community, and the general public on notice of the dangers and adverse effects caused by implantation of the Supris® sling.

79. The Supris® sling as designed, manufactured, distributed, sold and/or supplied by Defendants was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

FACTS SPECIFIC TO PLAINTIFF CRISTY DAVIS

80. Mrs. Davis was implanted with the Supris® sling on or about November 27, 2018, which was designed, manufactured, packaged, labeled, distributed and sold by Defendants.

81. The Supris® sling was intended to treat Mrs. Davis for vaginal wall prolapse, the use for which Defendants marketed the product.

82. Mrs. Davis's treating physicians implanted the Supris® sling in the manner in which they were instructed and directed, and therefore properly and appropriately.

83. The Supris® sling was designed to be placed:

a. Into the obturator internus muscle which is adjacent to the pudendal nerve and caused Plaintiff's injuries, *inter alia* symptoms of pudendal neuralgia, including tailbone pain, pelvic bone pain, pain in her perineum that limited sitting tolerance, painful bladder filling, de novo urinary urgency without objective retention, numbness of her clitoris, impaired mobility, anorectal pain, and dyspareunia.

b. Blindly, not accounting for anatomic variations of the pudendal nerve or the obturator nerve.

c. In close proximity to the obturator nerve, causing Plaintiff's injuries, *inter alia*, symptoms of obturator

neuralgia including groin pain and impairments in mobility.

d. Into the groin and obturator internus, thereby causing Plaintiff's injuries, *inter alia*, symptoms of hip abductor myalgia, including groin pain and pain with gait.

e. On or about the pelvic floor, thereby piercing muscles of the pelvic floor and other soft tissues resulting in exquisitely tender areas during vaginal examination. Operative findings and pathology study revealed foreign body giant cell reaction and minimal chronic inflammation and extensive scarring of the mid urethra with partial bladder outlet obstruction and encased in a dense scar plate with bridging fibrosis.

f. On or about the pelvic floor adjacent to the vagina, the urethra, the bladder, and obturator foramen causing Plaintiff's injuries and symptoms of chronic pelvic pain, impaired mobility, impaired sitting tolerance, tailbone pain, painful bladder filling, dyspareunia, groin pain, pelvic pain, anorectal pain, and mental and emotional distress.

84. The Supris® sling's design requires blind placement of the arms of the sling into the obturator foramen and obturator internus muscle and does not account for anatomic variations of the pudendal nerve and obturator nerve.

85. The Supris® sling was designed to be permanently implanted into a woman's body yet the product changes after implantation: it contracts over time which can cause fibrosis of muscles resulting in

irritation or injury to muscles, adhesions and scar tissue, inflammation, and pull or compress nerves thereby impairing sexual function and mobility, and cause bowel and bladder dysfunction function, chronic pelvic pain, and chronic groin pain. These changes occurred in Plaintiff and the Supris® sling implanted in Plaintiff was degraded on explant with findings of chronic inflammation.

86. Mrs. Davis developed multiple medical conditions which were caused by the Supris® sling implant including, but not limited to, groin pain, pain with sitting, tailbone pain, de novo dyspareunia, pelvic pain, anorectal pain, painful bladder filling, constipation, inability to wear close fitting pants, clitoral numbness, impaired mobility, limited sitting tolerance, dysuria, perineal pain, de novo urinary urgency without objective retention, requiring a Kelly plication (a non-mesh treatment of stress urinary incontinence at the time of transvaginal excision of the mesh), partial bladder outlet obstruction, and stress incontinence.

87. At all times material hereto, Defendants failed to comply or properly comply with state and/or Federal law in connection with the Supris® sling.

88. The risk of serious injuries, including life-altering, on-going pain, was known or should have been known to Defendants, but in spite of these risks, Defendants deliberately concealed these risks and, instead, represented that the product was safe and effective and continued to market the Supris® sling for transvaginal use to physicians and patients, including Mrs. Davis and Plaintiff's healthcare providers, without adequate warnings.

89. Mrs. Davis reasonably relied upon the representations of Defendants and had the Supris® sling implanted in her body.

90. Had Defendants properly disclosed the risks associated with the Supris® sling, Mrs. Davis would not have used it.

91. The injuries suffered by Mrs. Davis were caused by the wrongful acts, omissions, and false representations of Defendants.

92. As a result of having the Supris® sling implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury and symptoms including, but not limited to, groin pain, pain with sitting, tailbone pain, de novo dyspareunia, pelvic pain, anorectal pain, painful bladder filling, constipation, inability to wear close fitting pants, clitoral numbness, impaired mobility, limited sitting tolerance, dysuria, perineal pain, and de novo urinary urgency without objective retention, partial bladder outlet obstruction, and stress incontinence.

93. Plaintiff has undergone medical treatments and surgical procedures related to failure of the device, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

94. All of the physical injury and tremendous emotional distress that Mrs. Davis suffered could have been prevented if Defendants had placed the health and safety of the public, including Mrs. Davis, above their own profits.

FIRST CAUSE OF ACTION

STRICT PRODUCT LIABILITY - CONSUMER EXPECTATIONS TEST

(By Plaintiff Cristy Davis Against All Defendants)

95. Plaintiff repeats, realleges and incorporates by reference each and all of the allegations contained in paragraphs 1 through 94,

inclusive, of this complaint, and by this reference incorporate the same into this cause of action herein.

96. Defendants manufactured, sold and/or distributed the Product to Mrs. Davis to be used for the treatment of Pelvic Organ Prolapse.

97. Defendants manufacturing process and the raw materials used for their Product resulted in product defects.

98. At all times relevant herein, the Product failed to perform as safely as an ordinary customer would expect when used in its intended or reasonably foreseeable manner.

99. As a result of the implantation of the Product, Mrs. Davis suffered debilitating injuries resulting in groin pain, pain with sitting, tailbone pain, de novo dyspareunia, pelvic pain, anorectal pain, painful bladder filling, constipation, inability to wear close fitting pants, clitoral numbness, impaired mobility, limited sitting tolerance, dysuria, perineal pain, de novo urinary urgency without objective retention, partial bladder outlet obstruction, and stress incontinence, and the need for additional surgery and future therapeutic treatments.

100. At all times herein mentioned the Product was used in its original condition and as intended by Defendants and in a manner foreseeable to Defendants.

101. As a result of the defective condition of the Product, Mrs. Davis has suffered the economic and non-economic losses in an amount to be proven at the time of trial.

102. In doing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of Mrs. Davis and others. Said

wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages.

103. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Product, Plaintiff was injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment in mobility and sexual function, impairment in bowel and bladder function, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

SECOND CAUSE OF ACTION

STRICT PRODUCT LIABILITY - RISK-BENEFIT TEST

(By Plaintiff Cristy Davis Against All Defendants)

104. Plaintiff repeats, realleges and incorporates by reference each and all of the allegations contained in paragraphs 1 through 103, inclusive, of this complaint, and by this reference incorporate the same into this cause of action herein.

105. Defendants manufactured, sold and/or distributed the Product to Mrs. Davis to be used for the treatment of Pelvic Organ Prolapse.

106. Defendants manufacturing process and the raw materials used for their Product resulted in product defects.

107. At all times relevant herein, the design of the product, including the use of the raw materials, included an inherent risk of danger to the consumers, including Mrs. Davis.

108. At all times relevant herein, the benefits of the design of the Product, as outline hereinabove, did not outweigh the risk of the danger inherent in the design of the Product.

109. At all times relevant herein, there were other feasible available alternative designs for products to treat pelvic organ prolapse, including but not limited to the use of a pessary for POP.

110. As a result of the implantation of the Product, Mrs. Davis suffered debilitating injuries resulting in groin pain, pain with sitting, tailbone pain, de novo dyspareunia, pelvic pain, anorectal pain, painful bladder filling, constipation, inability to wear close fitting pants, clitoral numbness, impaired mobility, limited sitting tolerance, dysuria, perineal pain, de novo urinary urgency without objective retention, partial bladder outlet obstruction, and stress incontinence, and the need for additional surgery and future therapeutic treatments.

111. At all times herein mentioned the Product was used in its original condition and as intended by Defendants and in a manner foreseeable to Defendants.

112. As a result of the defective condition of the Product, Mrs. Davis has suffered the economic and non-economic losses in an amount to be proven at the time of trial.

113. In doing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of Mrs. Davis and others. Said wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages.

114. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Product, Plaintiff was injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment in mobility and sexual function, impairment in bowel and bladder function, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

THIRD CAUSE OF ACTION

STRICT LIABILITY - FAILURE TO WARN

(By Plaintiff Cristy Davis Against All Defendants)

115. Plaintiff repeats, realleges and incorporates by reference each and all of the allegations contained in paragraphs 1 through 89, inclusive, of this complaint, and by this reference incorporate the same into this cause of action herein.

116. Defendants manufactured, sold and/or distributed the Product to Mrs. Davis to be used for the treatment of Pelvic Organ Prolapse.

117. Defendants manufacturing process and the raw materials used for their Product resulted in product defects.

118. At all times mentioned herein, the Product was and is dangerous and presented a substantial danger to patients who were implanted with the Product, and these risks and dangers were known or knowable at the time of distribution and implantation in Mrs. Davis. Ordinary consumers would not have recognized the potential risks and dangers the Product posed to pelvic reconstruction patients because its uses were specifically promoted to improve the health of such patients. The Product was used in a way reasonably foreseeable to Defendants by Mrs. Davis. The Product was surgically place in the

appropriate position in Mrs. Davis. Defendants failed to provide warnings of such risks and dangers to Mrs. Davis as described herein.

119. Mrs. Davis would not have consented to use the Supris® sling had Defendants given adequate warnings to Mrs. Davis and Plaintiff's implanting physicians.

120. As a result of the implantation of the Product, Mrs. Davis suffered debilitating injuries resulting in groin pain, pain with sitting, tailbone pain, de novo dyspareunia, pelvic pain, anorectal pain, painful bladder filling, constipation, inability to wear close fitting pants, clitoral numbness, impaired mobility, limited sitting tolerance, dysuria, perineal pain, de novo urinary urgency without objective retention, partial bladder outlet obstruction, and stress incontinence, and the need for additional surgery and future therapeutic treatments.

121. At all times herein mentioned the Product was used in its original condition and as intended by Defendants and in a manner foreseeable to Defendants.

122. As a result of the defective condition of the Product, namely the lack of sufficient warnings, Mrs. Davis has suffered the economic and non-economic losses in an amount to be proven at the time of trial.

123. In doing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of Mrs. Davis and others. Said wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages.

124. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Product, Plaintiff was injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment in mobility and sexual function, impairment in bowel and bladder function, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

FOURTH CAUSE OF ACTION

STRICT LIABILITY - MANUFACTURING DEFECT

(By Plaintiff Cristy Davis Against All Defendants)

125. Plaintiff repeats, realleges and incorporates by reference each and all of the allegations contained in paragraphs 1 through 99, inclusive, of this complaint, and by this reference incorporate the same into this cause of action herein.

126. At all times herein mentioned, Defendants Product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to them. The Supris® sling was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale, and distribution. The properties of polypropylene mesh, especially the stiffer polypropylene mesh with small pore size used in the Supris® sling, is unsuitable for use at the time it left the possession of the Defendants. Not by way of limitation, the product differed from Defendants intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

127. As represented by Defendants, the Product, when properly manufactured as designed and intended by Defendants is inert. The Product that was implanted in the plaintiff was not inert, but rather

contracted and degraded upon implant. As a proximate and legal result of the defective condition of the Product, Mrs. Davis was caused to suffer and will continue to suffer economic and non-economic losses in an amount to be proven at the time of trial.

128. In doing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of Mrs. Davis and others. Said wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages.

129. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Product, Plaintiff was injured catastrophically, an sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

FIFTH CAUSE OF ACTION

NEGLIGENCE

(By Plaintiff Cristy Davis Against All Defendants)

130. Plaintiff repeats, realleges and incorporates by reference each and all of the allegations contained in the preceding paragraphs of this Complaint, and by this reference incorporate the same into this cause of action herein.

131. At all times herein mentioned, Defendants, were engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, supplying, promoting, selling,

marketing, warranting, packaging and advertising the Product and/or directing Physicians and Surgeons how to use and implant the Product.

132. Defendants owed to Mrs. Davis and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and Defendants breached said duty of care.

133. At all times relevant hereto, Defendants owed to Mrs. Davis and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, instruction and direction on implantation, use, issuance of warnings with respect to promotion, advertising, sale, and safety monitoring of the Product, and to adequately test and warn of the risk and dangers of the Product, both before and after sale.

134. Additionally, Defendants owed to Mrs. Davis and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Product manufactured, used, distributed, sold, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Product to perform as intended or as an ordinary consumer would expect.

135. At all times relevant hereto, Defendants breached the aforementioned duties in that it negligently and carelessly manufactured, fabricated, designed, licensed, produced, compounded, assembled, inspected or failed to inspect, tested or failed to test, warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, advertised, instructed on the manner and method of

implantation and surgery, the Product in that said Product caused, directly and proximately, the injuries of Mrs. Davis through failure of the Product to perform as intended or as an ordinary consumer would expect.

136. Defendants' manufacturing process and the raw materials used for the Supris® sling resulted in product defects.

137. The acts of Defendants constitute violations of the duty of ordinary care and skill owed by Defendants to Mrs. Davis and/or her physicians.

138. Plaintiff used, handled, or was implanted with Defendants' Product referred herein in a manner that was intended and reasonably foreseeable by Defendants.

139. As the direct and proximate result of Defendants' breach of its aforementioned duties with respect to the Supris® sling, Mrs. Davis suffered the economic and non-economic losses in an amount to be proven at the time of trial.

140. In doing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of the Plaintiff and others. Said wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages.

141. As a proximate result of the oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of the Plaintiff and other, Plaintiff was injured catastrophically, an sustained severe and permanent pain, suffering, disability,

impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS AND IMPLIED WARRANTIES

(By Plaintiff Cristy Davis Against All Defendants)

142. Plaintiff repeats, realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint, and by this reference incorporates the same into this cause of action as though fully stated herein.

143. Defendants manufactured, sold and/or distributed the Product to Mrs. Davis to be used for the treatment of Pelvic Organ Prolapse.

144. Defendants manufacturing process and the raw materials used for their Product resulted in product defects.

145. At all relevant times, Defendants were in the business of manufacturing, selling, advertising, marketing, and providing the Product for the treatment of POP, and held themselves out as having special knowledge and skill regarding the slings, mesh, and treatment for POP, and the manufacture, sale, training, instruction, and implanting of surgical mesh products that they knew would be used by the public.

146. At all relevant times, Defendants, and each of them, knew and/or had reason to know that Plaintiff, and her physicians intended to use the Product for the ordinary and expected purposes, including, but not limited to, treatment of POP and/or SUI.

147. At all relevant times, Defendants, and each of them, knew and/or should have known that the Plaintiff and her physicians were relying on the skill and judgment of the Defendants, and each of

them, to treat her POP and/or SUI, and the Product was suitable and safe for these particular purposes.

148. Plaintiff and her physicians justifiably relied on the skill and judgment of the Defendants, and each of them, as they held themselves out as experienced product designers, manufacturers, instructors, trainers, and/or implanters of suitable and safe surgical mesh devices and/or products to treat Pelvic Organ Prolapse and/or Stress Urinary Incontinence.

149. Plaintiff is informed and believes, and thereupon alleges, that at all times herein mentioned, Defendants, and each of them, breached the above-described express and/or implied warranties, in that, inter alia, the Product was not of merchantable quality and production, was not free from design and manufacturing defects, was not of the same or safe quality as those acceptable in the trade/field, was not fit for the ordinary purpose for which surgical mesh/sling systems are used, and was not safe for the use for which it was intended.

150. By virtue of the foregoing and because, among other things, the Product's raw materials were subject to erosion, as referenced above herein, and was not "biocompatible," the Product was not suitable for said intended and/or particular purposes.

151. As a result of the breaches by Defendants, and each of them, of the above-described express and/or implied warranties, Plaintiff was caused to suffer severe and permanent injuries and harm, and these breaches and the failure of the Scooter to have the expected fitness and quality was a substantial factor in causing Plaintiff's harm.

152. As a direct, proximate and legal result of the acts, conduct, and omissions of Defendants, and each of them, Plaintiff was injured and hurt in her health, strength and activity, sustaining injuries to her body and shock and injury to her nervous system and person, all of which said injuries have caused, and continue to cause Plaintiff great physical, mental and nervous pain and suffering in the past and in the future. Plaintiff is informed and believes and thereupon alleges, that said injuries will result in some permanent disability to her, and general damages, past and future, in an amount which will be stated according to proof, pursuant to California Code of Civil Procedure § 425.10, and in an amount which is in excess of the jurisdictional limits of this Court.

153. As a direct, proximate and legal result of the acts, conduct, and omissions of Defendants, and each of them, Plaintiff was compelled to and did employ the services of hospitals, physicians, surgeons, nurses, and the like to care for and treat her, and incurred hospital, medical and professional and incidental expenses in the past, and Plaintiff is informed and believes and thereupon alleges, that by reason of her injuries she will necessarily incur additional like expenses for an indefinite period of time in the future, the exact amount of which will be stated according to proof, pursuant to California Code of Civil Procedure § 425.10.

154. As a direct, proximate and legal result of the acts, conduct, and omissions of Defendants, and each of them, Plaintiff was prevented from attending to her usual occupation in the past, and Plaintiff is informed and believes, and thereupon alleges, that she will be prevented from attending to her usual occupation for a period of time in the future, and thereby will also sustain a loss of

earning capacity, in addition to lost earnings, past, present and future, in an amount unknown to Plaintiff at this time, and will be stated according to proof at a later time, pursuant to California Code of Civil Procedure § 425.10.

SEVENTH CAUSE OF ACTION

FRAUD

(By Plaintiff Cristy Davis Against All Defendants)

155. Plaintiff repeats, re-alleges and incorporates by reference each of the and all the allegations contained in the preceding paragraphs, inclusive, of this Complaint, and by this reference incorporate the same into this cause of action herein.

156. Defendants, from the time that the Product was first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations concerning the product and its related procedures, as previously set forth herein, to the Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, including, but not limited to, the misrepresentation of that the Product would not erode, cause inflammatory responses or infections, would not migrate, would not result in neuropathic and other acute and chronic nerve damages and pain for the treatment of pelvic organ prolapse and/or stress urinary incontinence.

157. The representations by said Defendants were, in fact, false. The true facts include, but are not limited to, that the Product was not safe to be used for treatment of urinary incontinence, pelvic organ prolapse, or vaginal vault prolapse, and was, in fact dangerous to the health and body of Plaintiff.

158. When the Defendants made these representations, they knew that they were false. Defendants made said representations with the intent to defraud and deceive Plaintiff, and with intent to induce Plaintiff to act in the manner herein alleged, that is to use the aforementioned product for treatment of urinary incontinence, pelvic organ prolapse, and/or vaginal vault prolapse.

159. At the time Defendants made the aforementioned representations, Plaintiff took the actions herein alleged; Plaintiff and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiff was induced to, and did, use the aforesaid product as herein described. If Plaintiff had known the actual facts, she would not have taken such action. The reliance of Plaintiff and her physicians upon Defendants' representations were justified because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

160. As a result of Defendants' fraud and deceit, Plaintiff was caused economic and noneconomic losses in an amount to be proven at trial.

161. In committing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of the Plaintiff and others. Said wrongful conduct was done with advance knowledge and/or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages pursuant to Cal. Civil Code § 3294. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use

of the Product as described herein. Defendants did not disclose this information to the Plaintiff, her health care providers, the health care community and the general public. Without full knowledge of the dangers of the Product, Plaintiff could not, through reasonable diligence, discover that she had a valid claim.

EIGHTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By Plaintiff Cristy Davis Against All Defendants)

162. Plaintiff repeats, re-alleges and incorporates by reference each and all of the allegations contained in the preceding paragraphs inclusive, of this Complaint, and by this reference incorporate the same into this cause of action herein.

163. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, to Plaintiff Cristy Davis, her physicians and her other healthcare providers, and to the public that the Defendants' Product had been tested and had been determined to be safe and effective for treating stress urinary incontinence. Defendants' representations of safety and effectiveness as to their Product were false.

164. From the time that the Supris® sling was first tested, studied, researched, first manufactured, marketed and distributed, up to the present, Defendants made false representations concerning the product and its related procedures to Mrs. Davis, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general.

165. Defendants failed to exercise ordinary care in their representations concerning their Product because they negligently

concealed, omitted and misrepresented the Product's high risk of unreasonable, dangerous, adverse side effects.

166. The misrepresentations included, but were not limited to, the misrepresentation that the Product was inert, safe, fit, effective, permanent, would not cause inflammatory responses or infections, would not migrate and would not result in neuropathic and other acute and chronic nerve damage and pain for the treatment of stress urinary incontinence.

167. At all times relevant hereto, Defendants conducted a sales and marketing campaign to promote the sale of the Product and willfully deceived Mrs. Davis, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the health risks and consequences of the use of the Product including but not limited to making the false representations as outlined in the preceding paragraph.

168. Defendants made the foregoing misrepresentations without any reasonable ground for believing them to be true. These misrepresentations were made directly by Defendants, their sales wholesalers, distributors representatives, detail persons and other authorized agents of said Defendants, and in publications and other written materials directed to Mrs. Davis, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general with the intention of inducing reliance and the purchase and implantation of the Product.

169. Defendants knew, or should have known, that the Product had been insufficiently tested, or had not been tested at all, lacked

adequate and accurate warnings, and created a high risk, or higher than acceptable risk, or higher than reported and represented risk, of adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually.

170. The foregoing representations by Defendants about their Product were false in that the Product is not, and at all relevant times alleged herein was not, inert, safe, fit, effective, or permanent, would not cause inflammatory responses or infections, would not migrate and would not result in neuropathic and other acute and chronic nerve damage and pain for the treatment of stress urinary incontinence.

171. When used for treatment of stress urinary incontinence, indeed, the use of the Product is hazardous to health, and the Product has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Mrs. Davis as described herein. The foregoing misrepresentations by Defendants were made with the intention of inducing reliance and inducing the purchase and implantation of Product.

172. In reliance on the misrepresentations of Defendants, Plaintiff and her prescribing physicians and healthcare providers were reasonably induced to purchase and use the Product. If they had known of the true facts and the facts concealed by Defendants, they would not have used the Product. Their reliance upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

173. Mrs. Davis reasonably relied upon the representations of Defendants and had the Supris® sling implanted in her body.

174. Had Defendants properly disclosed the risks and the magnitude of risk including life-altering pain associated with the Supris® sling, Mrs. Davis and her physicians would not have used it.

175. Had Defendants properly disclosed the risks and the magnitude of risk including life-altering pain associated with the Supris® sling compared with safer alternative procedures and safer alternative designs, Mrs. Davis and her physicians would not have used it.

176. As a result of Defendants' false misrepresentations as set forth above, Plaintiff sustained both economic and non-economic injuries in an amount to be proven at the time of trial.

177. In doing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of the Plaintiff and others. Said wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages.

178. As a proximate result of the negligent misrepresentation, Plaintiff was injured catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

NINTH CAUSE OF ACTION

FRAUD BY CONCEALMENT

(By Cristy Davis Against All Defendants)

179. Plaintiff repeats, re-alleges and incorporates by reference each and all of the allegations contained in the preceding paragraphs inclusive of this Complaint, and by this reference incorporate the same into this cause of action herein.

180. At all times mentioned herein, Defendants had the duty and obligations to disclose to Plaintiff and her physicians the true facts concerning the Product, that is, that said product was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendants made the affirmative representations as set forth above to Plaintiff and their physicians and the general public prior to the date that the Product was implanted in Plaintiff, while concealing material facts.

181. At all times mentioned herein, Defendant willfully and maliciously concealed facts as set forth above from Plaintiff and her physician, and therefore Plaintiff, with the intent to defraud as herein alleged.

182. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have reasonably relied upon said representations of safety and efficacy and utilized the Product for correction of urinary incontinence, pelvic organ prolapse, or vaginal vault prolapse. Defendants' misrepresentations were a substantial fact in Plaintiff utilizing the Product for correction of her medical condition.

183. As a result of the concealment of the facts set forth above, Plaintiff sustained economic and non-economic damages in an amount to be proven at the time of trial.

184. In committing the acts herein, the Defendants acted with oppression and/or fraud and/or malice demonstrating a conscious disregard for the rights and safety of the Plaintiff and others. Said wrongful conduct was done with advance knowledge and/or authorization and/or was ratified by an officer, director and/or managing agent of the Defendants and warrants the imposition of an award of punitive damages pursuant to Cal. Civil Code § 3294. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of the Product as described herein. Defendants did not disclose this information to the Plaintiff, her health care providers, the health care community and the general public. Without full knowledge of the dangers of the Product, Plaintiff could not, through reasonable diligence, discover that she had a valid claim.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. For past and future economic/special damages in an amount which will conform to proof at time of trial;
2. For past and future non-economic and general damages, according to proof at the time of trial;
3. For punitive and exemplary damages in an amount to be determined at trial (except for the Fifth or Eighth Causes of Action);
4. For injunctive relief, enjoining Defendant from the acts of unfair competition and untrue and misleading advertising; and
5. For such other and further relief as the Court may deem just and proper, including costs and prejudgment interest.
6. For attorney's fees pursuant to statute.

DATED: May 23, 2022

THE DOLAN LAW FIRM

Christopher B. Dolan, Esq.
Allison L. Stone, Esq.
Cioffi C. Remmer, Esq.
Taylor French, Esq.
Attorneys for Plaintiff,
CRISTY DAVIS

JURY DEMAND

Plaintiff demands a trial by jury on all causes of action which

may be tried by a jury.

DATED: May 23, 2022

THE DOLAN LAW FIRM

Christopher B. Dolan, Esq
Allison L. Stone, Esq.
Cioffi C. Remmer, Esq.
Taylor French, Esq.
Attorneys for Plaintiff,
CRISTY DAVIS

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Christopher B. Dolan, Esq. (165358) / Cioffi C. Remmer, Esq. (262663)
DOLAN LAW FIRM, PC, 1438 Market Street, San Francisco, CA 94102
TELEPHONE NO.: 415-421-2800 FAX NO. (Optional): 415-281-2830
E-MAIL ADDRESS: cioffi.remmer@dolanlawfirm.com
ATTORNEY FOR (Name): Cristy Davis

FOR COURT USE ONLY

FILED
MAY 31 2022
K. SIEVER CLERK OF THE COURT
SUPERIOR COURT OF CALIFORNIA
COUNTY OF CONTRA COSTA
By M. Mackenzie Deputy Clerk

SUPERIOR COURT OF CALIFORNIA, COUNTY OF CONTRA COSTA
STREET ADDRESS: 725 Court Street
MAILING ADDRESS: 725 Court Street
CITY AND ZIP CODE: Martinez 94553
BRANCH NAME: Wakefield Taylor Courthouse

CASE NAME: Davis v. Coloplast A/S, et al.

CIVIL CASE COVER SHEET
[X] Unlimited (Amount demanded exceeds $25,000) [ ] Limited (Amount demanded is $25,000 or less)

Complex Case Designation
[ ] Counter [ ] Joinder
Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

CASE NUMBER: C22-01086
JUDGE:
DEPT:

Items 1–6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort
[ ] Auto (22)
[ ] Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
[ ] Asbestos (04)
[X] Product liability (24)
[ ] Medical malpractice (45)
[X] Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
[X] Business tort/unfair business practice (07)
[ ] Civil rights (08)
[ ] Defamation (13)
[X] Fraud (16)
[ ] Intellectual property (19)
[ ] Professional negligence (25)
[ ] Other non-PI/PD/WD tort (35)

Employment
[ ] Wrongful termination (36)
[ ] Other employment (15)

Contract
[X] Breach of contract/warranty (06)
[ ] Rule 3.740 collections (09)
[ ] Other collections (09)
[ ] Insurance coverage (18)
[ ] Other contract (37)

Real Property
[ ] Eminent domain/Inverse condemnation (14)
[ ] Wrongful eviction (33)
[ ] Other real property (26)

Unlawful Detainer
[ ] Commercial (31)
[ ] Residential (32)
[ ] Drugs (38)

Judicial Review
[ ] Asset forfeiture (05)
[ ] Petition re: arbitration award (11)
[ ] Writ of mandate (02)
[ ] Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
[ ] Antitrust/Trade regulation (03)
[ ] Construction defect (10)
[ ] Mass tort (40)
[ ] Securities litigation (28)
[ ] Environmental/Toxic tort (30)
[ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
[ ] Enforcement of judgment (20)

Miscellaneous Civil Complaint
[ ] RICO (27)
[ ] Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
[ ] Partnership and corporate governance (21)
[ ] Other petition *(not specified above)* (43)

2. This case [ ] is [X] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [ ] Large number of separately represented parties
   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [ ] Substantial amount of documentary evidence
   d. [ ] Large number of witnesses
   e. [ ] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. [X] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [X] punitive
4. Number of causes of action *(specify)*: Nine (9)
5. This case [ ] is [X] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: May 23, 2022
Christopher B. Dolan, Esq. / Cioffi C. Remmer, Esq.
(TYPE OR PRINT NAME) (SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Form Adopted for Mandatory Use
Judicial Council of California
CIVIL CASE COVER SHEET
Cal. Rules of Court, rules 2.30, 3.220, 3.400–3.403, 3.740
Cal. Standards of Judicial Administration, std. 3.10

Exhibit A
068

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

CM-010

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the Civil Case Cover Sheet contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the Civil Case Cover Sheet to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
- Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition

For your protection and privacy, please press the Clear

Exhibit A

069

Superior Court of California, Contra Costa County

CV - Martinez-Wakefield Taylor Courthouse
725 Court Street
Martinez CA 94553
925-608-1000
www.cc-courts.org

K. Bieker
Court Executive Officer

CASE NAME:	CASE NUMBER:
CHRISTY DAVIS VS. COLOPLAST A/S	C22-01086

1. NOTICE IS HEREBY GIVEN THAT A CASE MANAGEMENT CONFERENCE IS SET IN THE ABOVE ENTITLED CASE AND WILL BE HELD IN THIS COURT ON:

HEARING DATE:	HEARING TIME:	HEARING LOCATION:
09/26/2022	8:30 AM	DEPARTMENT 07 725 COURT ST RM 209 MARTINEZ, CA 94553

THIS FORM, A COPY OF THE NOTICE TO PLAINTIFFS, THE ADR INFORMATION SHEET, A BLANK CASE MANAGEMENT CONFERENCE QUESTIONNAIRE, AND A BLANK STIPULATION FORM ARE TO BE SERVED ON OPPOSING PARTIES. ALL PARTIES SERVED WITH SUMMONS AND COMPLAINT/CROSS-COMPLAINT OR THEIR ATTORNEY OF RECORD MUST APPEAR.

2. YOU MAY STIPULATE TO AN EARLIER CASE MANAGEMENT CONFERENCE. IF ALL PARTIES AGREE TO AN EARLY CASE MANAGEMENT CONFERENCE, PLEASE CONTACT THE COURT CLERK'S OFFICE AT (925)608-1000 FOR UNLIMITED CIVIL AND LIMITED CIVIL CASES FOR ASSIGNMENT OF AN EARLIER DATE.
3. YOU MUST BE FAMILIAR WITH THE CASE AND BE FULLY PREPARED TO PARTICIPATE EFFECTIVELY IN THE CASE MANAGEMENT CONFERENCE AND TO DISCUSS THE SUITABILITY OF THIS CASE FOR THE EASE PROGRAM, PRIVATE MEDIATION, BINDING OR NON-BINDING ARBITRATION, AND/OR USE OF A SPECIAL MASTER.
4. AT ANY CASE MANAGEMENT CONFERENCE THE COURT MAY MAKE PRETRIAL ORDERS INCLUDING THE FOLLOWING:
   a) AN ORDER ESTABLISHING A DISCOVERY SCHEDULE
   b) AN ORDER REFERRING THE CASE TO ARBITRATION
   c) AN ORDER TRANSFERRING THE CASE TO LIMITED JURISDICTION
   d) AN ORDER DISMISSING FICTITIOUS DEFENDANTS
   e) AN ORDER SCHEDULING EXCHANGE OF EXPERT WITNESS INFORMATION
   f) AN ORDER SETTING SUBSEQUENT CONFERENCE AND THE TRIAL DATE
   g) AN ORDER CONSOLIDATING CASES
   h) AN ORDER SEVERING TRIAL OF CROSS-COMPLAINTS OR BIFURCATING ISSUES
   i) AN ORDER DETERMINING WHEN DEMURRERS AND MOTIONS WILL BE FILED

SANCTIONS

IF YOU DO NOT FILE THE CASE MANAGEMENT CONFERENCE QUESTIONNAIRE OR ATTEND THE CASE MANAGEMENT CONFERENCE OR PARTICIPATE EFFECTIVELY IN THE CONFERENCE, THE COURT MAY IMPOSE SANCTIONS (INCLUDING DISMISSAL OF THE CASE AND PAYMENT OF MONEY).

SUPERIOR COURT OF CALIFORNIA, CONTRA COSTA COUNTY

I DECLARE UNDER PENALTY OF PERJURY THAT I AM NOT A PARTY TO THE WITHIN ACTION OR PROCEEDING; THAT ON THE DATE BELOW INDICATED, I SERVED A COPY OF THE FOREGOING NOTICE BY DEPOSITING SAID COPY ENCLOSED IN A SEALED ENVELOPE WITH POSTAGE THEREON FULLY PREPAID IN THE UNITED STATES MAIL AT MARTINEZ, CALIFORNIA AS INDICATED ABOVE.

DATE: 5/31/2022

BY: _____
M. MACAPINLAC, DEPUTY CLERK